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SUBTITLE: Assessment of Dietary Calcium Intake, Physical Activity and Habits Affecting Skeletal Health Among Premenopausal Military Women Protocol 9

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The attainment of peak bone mass during the premenopausal years is critical in preventing osteoporosis later in life. The purpose of this study is to survey 1,000 active duty military premenopausal women in regards to skeletal health habits such as current levels of calcium intake, exercise, smoking, alcohol intake, menstrual regularity, and parity. We further wish to measure bone density in a subset of 100 women to determine which factors correlate best with optimal peak bone mass. Thus far, 1,645 questionnaires have been mailed and 35% have been returned. In addition, 42 have been recruited to have bone density measurements. The data collected is being tabulated but has not yet been analyzed.

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Michael T McDermott 16 Aug 95

PI - Signature Date

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Introduction

The attainment of maximal peak bone mass in the premenopausal years is important in the prevention of postmenopausal osteoporosis. Peak bone mass, which occurs at approximately age 35 years in women, appears to be an important determinant of the risk of developing postmenopausal osteoporosis. Three factors are considered major contributors to the development of peak bone mass: genetics, calcium intake and physical activity. Additionally a number of adverse risk factors including smoking, alcohol consumption and caffeine consumption may have detrimental effects during this period. Numerous studies in adolescents (1-7) and young adults (8-13) have shown that past and current calcium intake make a significant contribution to skeletal mass, while some have shown equivocal or no demonstrable beneficial effects (14-18). Exercise, similarly, has shown positive effects in teenagers (4,7) and young adults (9,10,13) in some but not all (14,16-18) studies. These topics have been the subject of recent extensive literature reviews which conclude that both calcium intake and physical activity are important for the development of optimal premenopausal bone mass (19-22). Broad based national surveys conducted from the 1970's until recently have consistently demonstrated that females of all ages, races and ethnic groups in the United States consume less than the recommended daily allowance (RDA) of calcium (23-26). There is much less information on the level of exercise and on smoking, alcohol intake and caffeine consumption in women in the

18-40 year old age group in this country. Furthermore such information has not, to our knowledge, been collected in active duty military women. There is reason to believe that active duty military women may differ from the general population, although there is no data to confirm this impression. Potential areas where differences may occur, at least in some military women, include living accommodations, dietary habits, smoking and alcohol habits, level of physical activity and exercise, participation in field training exercises, deployments and frequent moves. One recent study has suggested that active duty military women may have an increased risk of stress fractures and that smoking, amenorrhea and a family history of osteoporosis may be significant risk factors (27). In this study, questionnaires will be mailed to 1000 active duty premenopausal women selected randomly from personnel files.

Questionnaires will be approximately 2 pages long and will ask questions regarding daily and weekly intakes of specific high calcium foods and calcium supplements, performance of specific aerobic and resistive exercises, and daily quantity of smoking, consumption of alcoholic beverages and consumption of caffeine containing beverages. Participants will be asked to return their completed questionnaires to the investigators who will tabulate the data in order to determine the mean levels, ranges, standard deviations and standard errors of the study variables. If there are sufficient numbers, subgroup analysis according to job types, age, locations and marital status will be performed.

A subset of 100 participants who are stationed at nearby installations are being recruited to participate in a bone density study. All subjects will have blood drawn for a CBC and measurement of serum calcium, phosphorus, chloride, alkaline phosphatase, PTH and TSH and will have their bone density measured in the lumbar spine, femoral neck, mid-radius and distal radius by dual energy X-ray absorptiometry (DEXA). Site specific bone density values will then be correlated with the various skeletal health factors elicited on the questionnaires with standard multiple regression analyses.

It is also important to ascertain which factors are most closely related to site-specific skeletal development and maintenance. This information will be used to assess current skeletal health habits among premenopausal military women and to plan programs and measures to improve skeletal health in this population.

Body

A total of 1,640 questionnaires have been mailed to active duty women in the continental United States as of July 31, 1995. Of these, approximately 600 have been returned for a response rate of 35%. Names and mailing addresses of active duty women have been obtained from military installations in Colorado, Wyoming, Kansas, Missouri and Arizona and it is anticipated that a total of 3,000 questionnaires will be mailed to achieve the target of 1,000 questionnaires from which data will be tabulated. Prior to mailing, the questionnaires were screened by ten individuals to ensure that the questions and formats were easily understandable. In addition, the questionnaires are validated by personal interviews with the 100 individuals included in the subset of volunteers to undergo further study as described above. One hundred individuals from nearby military installations who completed the above questionnaire were recruited to undergo further study with bone related laboratory testing and bone density determinations. These individuals also undergo a physical examination including body fat content determination using caliper measurements. Approval was also received to further test these individuals body fat content using bioelectrical impedance which was measured after the individuals signed a separate consent form. A second questionnaire was also completed by these individuals which asked them to recall calcium intake during their high school years.

As the data is in the process of being assembled, no

analysis of the data will be undertaken at this point. It is felt based on the responses to the validated questionnaires that the information gained from the study will be accurate and useful in meeting the objectives outlined for this study.

Conclusions

Data collection from the calcium intake, physical activity, and habits questionnaires sent to active duty women is progressing well with approximately 35% of the 1,640 mailed questionnaires having been returned as of July 31, 1995. Forty-two individuals have so far been recruited to participate in the subset of 100 volunteers to undergo physical examination, laboratory testing and bone density determinations. As data is still being collected no analysis of the received data will be performed at this time. It is anticipated that through further mailing for a total of 3,000 questionnaires, that the study objective of 1,000 questionnaires will be easily attainable.

References:

1. Lloyd T, Andon MB, Rollings N, et al. Calcium supplementation and bone mineral density in adolescent girls. JAMA 270:841-4, 1993.

2. Grimston SK, Morrison K, Harder JA, Hanley DA. Bone mineral density during puberty in western Canadian children. Bone Miner 19:85-96, 1992.

3. Johnston Jr CC, Miller JZ, Slemenda CW, et al. Calcium supplementation and increases in bone mineral density in children. N Engl J Med 327:82-7, 1992.

4. Turner JG, Gilchrist NL, Ayling EM, Hassal AJ, Hooke EA, Saler WA. Factors affecting bone mineral density in high school girls. N Z Med J 105:95-6, 1992.

5. Sentipal JM, Wardlaw GM, Mahan J, Matknvic V. Influence of calcium intake and growth indexes on vertebral bone mineral density in young females. Am J Clin Nutr 54:425-8, 1991.

6. Chan GM. Dietary calcium and bone mineral status of children and adolescents. Am J Dis Child 145:631-4, 1991.

7. Rubin K, Schirduan V, Gendreau P, Sarfarazi M, Mendola R, Dalsky G. Predictors of axial and peripheral bone mineral density in healthy children and adolescents, with special attention to the role of puberty. J Pediatr 123:863070, 1991.

8. Stracke H, Renner E, Knie G, Leidig G, Minne H, Federlin K. Osteoporosis and bone metabolic parameters in dependence upon calcium intake through milk and milk products. Eur J Clin Nutr 47:617-22, 1993.

9. Metz JA, Anderson JJ, Gallagher Jr PN. Intakes of calcium, phosphorus, and protein, and physical-activity level are related to radial bone mass in young adult women. Am J Clin Nutr 58:537-42, 1993.

10. Recker RR, Davies KM, Hinders SM, Heaney RP, Stegman MR, Kimmel DB. Bone gain in young adult women. JAMA 268:2403-8, 1992.

11. Lutz J, Ltsar R. Mother-daughter pairs: spinal and femoral bone densities and dietary intakes. Am J Clin Nutr 52:872-7, 1990.

12. Tylavsky FA, Bortz AD, Hancock RL, Anderson JJ. Familial resemblance of radial bone mass between premenopausal mothers and their college-age daughters. Calcif Tissue Int 45:267-72, 1989.

13. Halioua L, Anderson JJ. Lifetime calcium intake and physical activity habits: independent and combined effects on the radial bone of health premenopausal Caucasian women. Am J. Clin Nutr 49:534-41, 1989.

14. Katzman DK, Bachrach LK, Carter DR, Marcus R. Clinical and anthropometric correlates of bone mineral acquisition in health adolescent girls. J Clin Endocrinol Metab 73:1332-9, 1991.

15. Sowers MR, Clark MK, Hollis B, Wallace RB, Jannausch M. Radial bone mineral density in pre- and perimenopausal women: a prospective study of rates and risk factors for loss. J Bone Miner Res 7:647-57, 1992.

16. Cox ML, Khan SA, Gau DW, Cox SA, Hodkinson HM. Determinants of forearm bone density in premenopausal women: a study in one general practice. Br J Gen Pract 41:194-6, 1991.

17. Mazess RB, Barden HS. Bone density in premenopausal women: effects of age, dietary intake, physical activity, smoking, and birth-control pills. Am J Clin Nutr 53:132-42, 1991.

18. McCulloch RG, Bailey DA, Houston CS, Dodd BL. Effects of physical activity, dietary calcium intake and selected lifestyle factors on bone density in young women. Can Med Assoc J 142:221-7, 1990.

19. Toss G. Effect of calcium intake vs. other life-style factors on bone mass. J Intern Med 231:181-6, 1992.

20. Matkovic V. Calcium and peak bone mass. J Intern Med 231:151-60, 1992.

21. Cumming RG. Calcium intake and bone mass: a quantitative review of the evidence. Calcif Tissue Int 47:194-201, 1990.

22. Gutin B, Kasper MJ. Can vigorous exercise lay a role in osteoporosis prevention? a review. Osteoporosis Int 2:55-69, 1992.

23. National Center of Health Statistics. Plan and operation of the Second National health and Nutrition Examination Surgey, 1976-1980. Vital and Health Statistics. Series 1, No. 15 (DHEW publication no. (PHS)81-1317). Health Research Statistics and Technology. Washington, DC: US GPO, July 1981.

24. Block G, Dresser CM, Hartman AM, Carroll MD. Nutrient sources in the American diet: quantitative data from the NHANES II survey. Am J Epidemiol 122:13-26, 1985.

25. Looker AC, Loria CM, Carroll MD, McDowell MA, Johnson CL. Calcium intake of Mexican Americans, Cubans, Puerto Ricans, non-Hispanic whites and non-Hispanic blacks in the United States. J Am Diet Assoc 93:1274-9, 1993.

26. Eck LH, Hackett-Renner C. Calcium intake in youth: sex, age, and racial differences in NHANES II. Prev Med 21:473-82, 1992.

27. Friedl KE, Nuovo JA, Patience TH, Dettori JR. Factors associated with stress fracture in young Army women: indications for further research. Military Medicine 157:337-8, 1992.